

Appl. No.: 09/842,466
Amdt. dated 05/02/2005
Reply to Office action of March 3, 2005

REMARKS/ARGUMENTS

This Amendment is responsive to rejections presented in the final Office Action mailed March 3, 2005 in the above-referenced application. Claims 6 – 9, 11, 13 – 20, and 31 – 47 are pending and stand rejected. Claims 31 and 33 have been amended. No Claims have been added or cancelled by this Amendment.

Claims 6 – 9, 11, 13 – 17, and 31 – 44 are rejected under 35 U.S.C. 103(a) over Hampton, U.S. Pat. No. 5,089,270, and Claims 18 – 20 and 45 – 47 are rejected under 35 U.S.C. 103(a) over Hampton in view of Hoover, U.S. Pat. No. 5,464,631.

Hampton discloses a multi-colored tablet coated with a clear coating. The multi-coloration is achieved by combining a first powder material containing a first coloring agent with a second powder material containing a second coloring agent. The two powders are compressed to form a solid tablet having a demarcation line between the first material and the second material (col. 4, line 3 to col. 5, line 20). The two-colored tablet is subsequently coated with a clear gelatin layer. Thus, Hampton does not disclose or suggest the multi-colored continuous film coating layer of the invented preparation. In fact, Hampton's specific description of a clear coating layer teaches away from the multi-colored coating layer.

Hoover discloses a cylindrically shaped caplet that is inserted into the body of a differently-colored gelatin capsule to give the appearance of a bi-colored capsule (col. 5, lines 17-19 and 54 - 59). However, Hoover provides no disclosure or suggestion of a multi-colored continuous film layer. Thus, the disclosure of Hoover fails to cure the deficiencies of Hampton, and even the combination of the references fails to teach or suggest the multi-colored continuous film layer.

In response to the rejections in view of Hampton and Hoover, Applicants have previously noted the recitation of at least one significant structural element, namely the multi-colored continuous film coating layer, which is not taught or suggested by Hampton or Hoover, alone or in combination.

The Office has heretofore declined to give weight to the coating layer distinction on the basis that the distinction was recited in the process steps of product-by-process claims. However, the claimed solid preparation is recited as the product prepared by the steps of coating

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the solid preparation with a continuous film coating layer, and exposing the coating layer to radiation sufficient to result in first and second parts of the coating layer having different coloration. Thus, the resulting product necessarily has a continuous film coating layer having parts with different coloration. The coating layer is a structural element of the claimed preparation which should not be disregarded on the basis that the preparation is claimed in product-by-process format.

In order to further emphasize the presence of the multi-colored continuous film coating layer, independent Claims 31 and 33 have been amended to specifically recite the multi-colored continuous film coating layer. As such, the Claims now specifically and structurally recite the coating layer that distinguishes the claimed preparation from the tablets of the references. Support for the amendment is provided on page 9, lines 10-14 and 21-24. The specific recitation of the coating layer is merely an explicit textual recitation of the coating layer that necessarily resulted from the previously recited process steps of Claims 31 and 33, respectively. So, the scope of the Claims has not been changed and no new issues have been presented.

Whereas the claimed solid preparation comprises a continuous multi-colored film coating layer that is not taught or suggested by the references, considered alone or in combination, and whereas the claimed coating layer is a structural distinction that distinguishes the claimed preparation from the prior art, independent of the process by which it is made, the claimed preparation has been shown to be patentably distinct from the references, and it is submitted that the prior art rejections have been overcome.

Regarding the showing of criticality of the recited film layer required by the preceding Office Action, Applicants submit that criticality need not be demonstrated where the cited references fail to teach or suggest a recited element of the claimed invention. Nonetheless, for the sake of completeness, the showing of criticality presented in the Response dated December 7, 2004 is reiterated and is incorporated herein by reference.

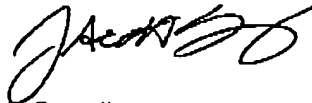
Applicants appreciate the Examiner's consideration of the amendments and remarks above which do not raise new issues, but which, instead, more clearly demonstrate the patentability of the pending claims over the cited references. In view of the amendments and remarks submitted above, it is respectfully submitted that the present claims are in condition for

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immediate allowance. It is therefore respectfully requested that a Notice of Allowance be issued. The Examiner is encouraged to contact Applicant's undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

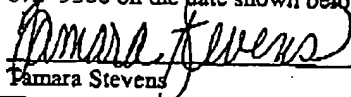


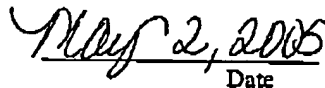
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